

automatic peritoneal dialysate delivery systems or “reverse osmosis” systems). Prepackaged dialysate intended for use with either of the peritoneal dialysate delivery systems is regulated by FDA as a drug.

(b) *Classification*. Class II (performance standards).

§ 876.5665 Water purification system for hemodialysis.

(a) *Identification*. A water purification system for hemodialysis is a device that is intended for use with a hemodialysis system and that is intended to remove organic and inorganic substances and microbial contaminants from water used to dilute dialysate concentrate to form dialysate. This generic type of device may include a water softener, sediment filter, carbon filter, and water distillation system.

(b) *Classification*. Class II (performance standards).

§ 876.5820 Hemodialysis system and accessories.

(a) *Identification*. A hemodialysis system and accessories is a device that is used as an artificial kidney system for the treatment of patients with renal failure or toxemic conditions and that consists of an extracorporeal blood system, a conventional dialyzer, a dialysate delivery system, and accessories. Blood from a patient flows through the tubing of the extracorporeal blood system and accessories to the blood compartment of the dialyzer, then returns through further tubing of the extracorporeal blood system to the patient. The dialyzer has two compartments that are separated by a semipermeable membrane. While the blood is in the blood compartment, undesirable substances in the blood pass through the semipermeable membrane into the dialysate in the dialysate compartment. The dialysate delivery system controls and monitors the dialysate circulating through the dialysate compartment of the dialyzer.

(1) The extracorporeal blood system and accessories consists of tubing, pumps, pressure monitors, air foam or bubble detectors, and alarms to keep blood moving safely from the blood access device and accessories for hemodialysis (§ 876.5540) to the blood com-

partment of the dialyzer and back to the patient.

(2) The conventional dialyzer allows a transfer of water and solutes between the blood and the dialysate through the semipermeable membrane. The semipermeable membrane of the conventional dialyzer has a sufficiently low permeability to water that an ultrafiltration controller is not required to prevent excessive loss of water from the patient's blood. This conventional dialyzer does not include hemodialyzers with the disposable inserts (Kiil type) (§ 876.5830) or dialyzers of high permeability (§ 876.5860).

(3) The dialysate delivery system consists of mechanisms that monitor and control the temperature, conductivity, flow rate, and pressure of the dialysate and circulates dialysate through the dialysate compartment of the dialyzer. The dialysate delivery system includes the dialysate concentrate for hemodialysis (liquid or powder) and alarms to indicate abnormal dialysate conditions. This dialysate delivery system does not include the sorbent regenerated dialysate delivery system for hemodialysis (§ 876.5600), the dialysate delivery system of the peritoneal dialysis system and accessories (§ 876.5630), or the controlled dialysate delivery system of the high permeability hemodialysis system § 876.5860).

(4) Remote accessories to the hemodialysis system include the unpowered dialysis chair without a scale, the powered dialysis chair without a scale, the dialyzer holder set, dialysis tie gun and ties, and hemodialysis start/stop tray.

(b) *Classification*. (1) Class II (performance standards) for hemodialysis systems and all accessories directly associated with the extracorporeal blood system and the dialysate delivery system.

(2) Class I for other accessories of the hemodialysis system remote from the extracorporeal blood system and the dialysate delivery system, such as the unpowered dialysis chair, hemodialysis start/stop tray, dialyzer holder set, and dialysis tie gun and ties. The devices subject to this paragraph (b)(2) are exempt from the premarket notification procedures in subpart E of part 807 of

§ 876.5830

21 CFR Ch. I (4–1–13 Edition)

this chapter subject to the limitations in § 876.9.

[48 FR 53023, Nov. 23, 1983, as amended at 54 FR 25050, June 12, 1989; 66 FR 38802, July 25, 2001]

§ 876.5830 Hemodialyzer with disposable insert (Kiil type).

(a) *Identification.* A hemodialyzer with disposable inserts (Kiil type) is a device that is used as a part of an artificial kidney system for the treatment of patients with renal failure or toxic conditions and that includes disposable inserts consisting of layers of semipermeable membranes which are sandwiched between support plates. The device is used with the extracorporeal blood system and the dialysate delivery system of the hemodialysis system and accessories (§ 876.5820).

(b) *Classification.* Class II (performance standards).

[48 FR 53023, Nov. 23, 1983, as amended at 53 FR 11253, Apr. 6, 1988]

§ 876.5860 High permeability hemodialysis system.

(a) *Identification.* A high permeability hemodialysis system is a device intended for use as an artificial kidney system for the treatment of patients with renal failure, fluid overload, or toxic conditions by performing such therapies as hemodialysis, hemofiltration, hemoconcentration, and hemodiafiltration. Using a hemodialyzer with a semipermeable membrane that is more permeable to water than the semipermeable membrane of the conventional hemodialysis system (§ 876.5820), the high permeability hemodialysis system removes toxins or excess fluid from the patient's blood using the principles of convection (via a high ultrafiltration rate) and/or diffusion (via a concentration gradient in dialysate). During treatment, blood is circulated from the patient through the hemodialyzer's blood compartment, while the dialysate solution flows countercurrent through the dialysate compartment. In this process, toxins and/or fluid are transferred across the membrane from the blood to the dialysate compartment. The hemodialysis delivery machine controls and monitors the pa-

rameters related to this processing, including the rate at which blood and dialysate are pumped through the system, and the rate at which fluid is removed from the patient. The high permeability hemodialysis system consists of the following devices:

(1) The hemodialyzer consists of a semipermeable membrane with an in vitro ultrafiltration coefficient (K_{uf}) greater than 8 milliliters per hour per conventional millimeter of mercury, as measured with bovine or expired human blood, and is used with either an automated ultrafiltration controller or another method of ultrafiltration control to prevent fluid imbalance.

(2) The hemodialysis delivery machine is similar to the extracorporeal blood system and dialysate delivery system of the hemodialysis system and accessories (§ 876.5820), with the addition of an ultrafiltration controller and mechanisms that monitor and/or control such parameters as fluid balance, dialysate composition, and patient treatment parameters (e.g., blood pressure, hematocrit, urea, etc.).

(3) The high permeability hemodialysis system accessories include, but are not limited to, tubing lines and various treatment related monitors (e.g., dialysate pH, blood pressure, hematocrit, and blood recirculation monitors).

(b) *Classification.* Class II. The special controls for this device are FDA's:

(1) "Use of International Standard ISO 10993 'Biological Evaluation of Medical Device—Part I: Evaluation and Testing,'" "

(2) "Guidance for the Content of 510(k)s for Conventional and High Permeability Hemodialyzers," "

(3) "Guidance for Industry and CDRH Reviewers on the Content of Pre-market Notifications for Hemodialysis Delivery Systems," "

(4) "Guidance for the Content of Pre-market Notifications for Water Purification Components and Systems for Hemodialysis," and

(5) "Guidance for Hemodialyzer Reuse Labeling." "

[65 FR 17145, Mar. 31, 2000]